K022670

510(k) Summary
for
Carrington Laboratories
CarraKlenz and UltraKlenz Wound Cleansers

OCT 17 2002

1. **SPONSOR**

Carrington Laboratories, Inc.
2001 Walnut Hill Lane
Irving, TX 75038

Contact Person: Fran Shull
Telephone: 972-714-5032

Date Prepared: October 9, 2002

2. **Device Name**

Proprietary Name:	CarraKlenz and UltraKlenz
Common/Usual Name:	Wound Cleansers
Classification Name:	Liquid Bandage

3. **PREDICATE DEVICES**

Alliclenz Wound Cleanser	K965120
Derma Sciences Dermagran Wound Cleanser with Zinc	K954743 and K945802

4. **DEVICE DESCRIPTION**

The Carrington CarraKlenz Wound Cleansers are wound cleaning solutions that are intended for the cleansing and irrigation of dermal wounds. The Carrington Wound Cleansers work by mechanical action on the dermal wounds. The pressure of the liquid flowing onto the wound aids in the removal of the debris from the wound. The Carrington Wound Cleansers are offered in various bottle sizes.

5. **INTENDED USE**

The Carrington Wound Cleansers are surfactant wound cleansers intended for the removal of foreign material such as dirt and debris from dermal wounds. CarraKlenz is a wound cleanser that is indicated for high, medium, and low exudating wounds.

K022670

UltraKlenz is a gentle wound cleanser which is used on intact skin.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Carrington Laboratories Wound Cleansers are substantially equivalent to the Allclenz Wound Cleanser cleared for marketing under K965120 and the Derma Sciences Dermagran Wound Cleanser with Zinc cleared under K954743 and K945802. All of the wound cleansers are intended for use on dermal wounds and abrasions and function by mechanical action on the wound to remove unwanted debris.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Carrington Laboratories, Inc.
Mary McNamara-Cullinane, RAC
c/o Medical Devices Consultants, Inc
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022670
Trade/Device Name: Carraklenz and Ultraklenz
Regulation Number: 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class I
Product Code: KMF
Dated: August 8, 2002
Received: August 12, 2002

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K022670

510(k) Number (if known): K022670

Device Name: Carrington Laboratories CarraKlenz and UltraKlenz Wound Cleansers

Indications for Use:

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CarraKlenz is a wound cleanser that is indicated for high, medium, and low exudating wounds.

UltraKlenz is a gentle wound cleanser which is used on intact skin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022670

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)